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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO.      | CONFIRMATION NO.       |
|---|-------------|---------------------------|--------------------------|------------------------|
| 10/764,417  | 01/23/2004  | Jannis G. Stavrianopoulos | Enz-61(D12)              | 8192                   |
| 28171 7590 09/10/2007<br>ENZO BIOCHEM, INC.<br>527 MADISON AVENUE (9TH FLOOR)<br>NEW YORK, NY 10022 |             |                           | EXAMINER<br>RILEY, JEZIA |                        |
|   |             |                           | ART UNIT<br>1637         | PAPER NUMBER           |
|   |             |                           | MAIL DATE<br>09/10/2007  | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/764,417

Applicant(s)

STAVRIANOPOULOS ET AL.

Examiner

Jezia Riley

Art Unit

1637

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 287-321 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 287-321 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/10/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 4/12/07 is acknowledged. The traversal is on the ground(s) that the dye and labeled target were not restricted in parent application 10/096075. This is found persuasive and all claims have been examined.

### *Specification*

The disclosure is objected to because of the following informalities: In page 1, the paragraph related to cross references is missing the serial numbers.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 287-321 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 287, for example, is vague and indefinite because of the recitation of the "capable of". It is unclear whether the claimed reactive group R actually does provide a conjugated system or an electron delocalized system, because having the capability is not the same thing as actually performing the function. A positive recitation is required.

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Claim 303, for example, is vague and indefinite because of the recitation of the **"capable of forming a carbon-carbon linkage"**. It is unclear whether the claimed reactive group R actually does form the carbon-carbon linkage with the target, because having the capability is not the same thing as actually performing the function. A positive recitation is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 287-291, 294-311, 314-321 are rejected under 35 U.S.C. 102(e) as being anticipated by Ju et al. US 6,664,079.

Ju et al. discloses a dye composition comprising a fluorescent dye linked to a moiety comprising an aromatic group which comprises a nitro substituent and an unsaturated group. Said composition is covalently attached to a target via a carbon-carbon linkage. Said target can be a nucleotide analog. The unsaturated group can be an alkyne group. The dye can comprise a charged or polar group, which inherently increases solubility. (See Figure 7).

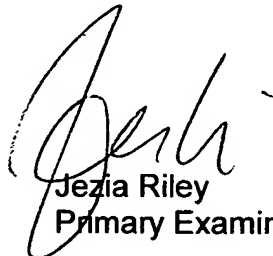
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/3/07

  
Jezia Riley  
Primary Examiner

|                                   |                                       |  |             |
|-----------------------------------|---------------------------------------|--|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>10/764,417 | Applicant(s)/Patent Under<br>Reexamination<br>STAVRIANOPOULOS ET AL. |             |
|                                   | Examiner<br>Jezia Riley               | Art Unit<br>1637   | Page 1 of 1 |

#### U.S. PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name      | Classification |
|---|---|--|-----------------|-----------|----------------|
| * | A | US-6,664,079                                     | 12-2003         | Ju et al. | 435/91.1       |
|   | B | US-  |                 |           |                |
|   | C | US-  |                 |           |                |
|   | D | US-  |                 |           |                |
|   | E | US-  |                 |           |                |
|   | F | US-  |                 |           |                |
|   | G | US-  |                 |           |                |
|   | H | US-  |                 |           |                |
|   | I | US-  |                 |           |                |
|   | J | US-  |                 |           |                |
|   | K | US-  |                 |           |                |
|   | L | US-  |                 |           |                |
|   | M | US-  |                 |           |                |

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| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | Classification |
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|   | R |  |                 |         |      |                |
|   | S |  |                 |         |      |                |
|   | T |  |                 |         |      |                |

#### NON-PATENT DOCUMENTS

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
|   | U |   |
|   | V |   |
|   | W |   |
|   | X |   |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

|   |                                  |                       |
|---|----------------------------------|-----------------------|
| Form PTO-1449, U.S. Department of Commerce<br>(REV. 8-83) Patent and Trademark Office<br><br>INFORMATION DISCLOSURE CITATION<br>(Use several sheets if necessary) | Atty. Docket No.<br>ENZ-61 (D12) | Serial No. 10/764,417 |
|   | Applicants: Ilan, et al          |                       |
|   | Filed: January 23, 2004          | Group: Not yet known  |

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE | NAME             | CLASS | SUB<br>CLASS | FILING<br>DATE IF<br>APPRO-<br>PRIATE |
|---------------------|-----------------|------|------------------|-------|--------------|---------------------------------------|
| /JR/                | 5 4 9 4 8 1 0   |      | Barany, et al    |       |              |                                       |
| /JR/                | 6 0 0 4 2 8 6   |      | Bellhouse, et al |       |              |                                       |
| /JR/                | 5 5 8 2 9 8 4   |      | Bieniarz, et al  |       |              |                                       |
| /JR/                | 5 5 9 9 9 3 2   |      | Bieniarz, et al  |       |              |                                       |
| /JR/                | 4 9 7 8 6 1 4   |      | Bronstein, IY    |       |              |                                       |
| /JR/                | 5 4 6 2 8 5 4   |      | Coassin, et al   |       |              |                                       |

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|---------------------|------------------|---------|---------------|-------|--------------|----------------------------|
| /JR/                | EP 0 6 6 7 3 9 3 | 8/16/95 | Rabbani et al | A1    |              |                            |
| /JR/                | EP 0 0 7 0 6 8 5 | 7/14/82 | Heller, et al | A1    |              |                            |

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|      |  |
|------|--|
| /JR/ | Ball, et al., "The use of tailed octamer primers for cycle sequencing," <u>Nucl. Acids. Res.</u> 26:5225-5227 (1998)   |
| /JR/ | Baranov, et al., "A new technique for the characterization of long-range tertiary contacts in large RNA molecules: insertion of a photolabel at a selected position in 16S rRNA within the Escherichia coli ribosome," <u>Nucl. Acids Res.</u> 25:2266-2273 (1997) |
| /JR/ | Dale, R.M., et al., "Direct covalent mercuration of nucleotides and polynucleotides," <u>Biochemistry</u> 14:2447-2457 (1975)  |
| /JR/ | Dale, R.M., et al., "The synthesis and enzymatic polymerization of nucleotide containing mercury: potential tools for nucleic acid sequencing and structural analysis," <u>Proc. Natl. Acad. Sci. USA</u> 70:2238-2242 (1973)                                      |
| /JR/ | Doan, T.L., et al., "Targeted cleavage of polynucleotides by complementary oligonucleotides covalently linked to iron-porphyrins," <u>Biochemistry</u> 25:6736-6739 (1986)   |
| /JR/ | Eglinton, G., et al., "A coupling of acetylenic compounds," <u>Adv. Organic Synthesis</u> 4:225-328 (1963)   |

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| EXAMINER /Jezia Riley/   | DATE CONSIDERED 09/03/2007 |
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| Form PTO-1449 U.S. Department of Commerce<br><br>(REV. 8-83) Patent and Trademark Office<br><br>INFORMATION DISCLOSURE CITATION<br>(use several sheets if necessary) | Atty. Docket No.<br>ENZ-61 (D12) | Serial No. 10/764,417 |
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|---------------------|-----------------|------|-------------------|-------|--------------|---------------------------------------|
| /JR/                | 5 8 4 9 4 8 0   |      | Cros, et al       |       |              |                                       |
| /JR/                | 4 8 9 4 3 2 5   |      | Engelhardt, et al |       |              |                                       |
| /JR/                | 5 2 4 1 0 6 0   |      | Engelhardt, et al |       |              |                                       |
| /JR/                | 5 2 8 8 6 0 9   |      | Engelhardt, et al |       |              |                                       |
| /JR/                | 6 2 2 1 5 8 1   |      | Engelhardt, et al |       |              |                                       |
| /JR/                | 4 3 7 5 9 7 2   |      | Forgione, et al   |       |              |                                       |
| /JR/                | 5 2 1 0 0 1 5   |      | Gelfand, et al    |       |              |                                       |

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|------|------------------|----------|----------------|-------|--------------|----------------------------|
| /JR/ | WO 9 9 2 8 5 0 0 | 11/27/98 | Lee, et al     |       |              |                            |
| /JR/ | EP 0 9 1 7 0 3 9 | 1/12/00  | Rabbani, et al | A1    |              |                            |

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|      | Enzo Biochem, Catalog Nos. 42722, 4723, 4724, New York, NY  |
| /JR/ | Ernst, et al., "Cyanine dye labeling reagents for sulfhydryl groups," <u>Cytometry</u> 10:3-10 (1989)   |
| /JR/ | Fuhrop, J.H., et al., Chapter 19 in "Porphyrins and Metalloporphyrins," ed. Smith, K.M., Elsevier Science, New York (1975)  |
| /JR/ | Kawase, et al., "Studies on nucleic acid interactions. I. Stabilities of mini-duplexes (dG2A4XA4G2-dC2T4YT4C2) and self-complementary d(GGGAAXYTTCCC) containing deoxyinosine and other mismatched bases," <u>Nucl. Acids. Res.</u> 14:7727-7736 (1986) |
| /JR/ | Kuhlmann, K.F., et al., "Synthesis, DNA-binding and biological activity of a double intercalating analog of ethidium bromide," <u>Nucl. Acids. Res.</u> 5:2629-2633 (1978)  |
| /JR/ | Larock, "Organomercurials in Organic Synthesis," <u>Tetrahedron</u> 38:1713-1754 (1982)   |

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|                     | 5 6 4 6 2 6 4   |      | Glazer, et al |       |              |                                       |
|                     | 5 2 4 8 6 1 8   |      | Haces, A.     |       |              |                                       |
|                     | 5 7 3 0 8 4 9   |      | Hamby, et al  |       |              |                                       |
|                     | 4 7 0 7 4 5 4   |      | Hendrix, JL   |       |              |                                       |
|                     | 5 4 6 4 7 4 1   |      | Hendrix, JL   |       |              |                                       |
|                     | 5 9 9 4 0 5 6   |      | Higuchi, RG   |       |              |                                       |
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| EP | 1 3 4 4 8 3 5   | 11/17/03 | Rabbani, et al | A1    |              |                            |

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| /JR/ | Liu, H., et al., "PCR amplification using deoxyinosine to replace an entire codon and at ambiguous positions," <u>Biotechniques</u> 16:24-26 (1994)   |
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| /JR/ | Loakes, D., et al., "5-Nitroindole as an universal base analogue," <u>Nucl. Acids Res.</u> 22:4039-4043 (1994)  |
| /JR/ | Loakes, D., "The applications of universal DNA base analogues," <u>Nucl. Acids Res.</u> 29:2437-2447 (2001)   |

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| /JR/                | 6 2 2 8 5 7 8   |      | Impraim, et al |       |              |                                       |
| /JR/                | 5 5 5 4 5 1 6   |      | Kacien, et al  |       |              |                                       |
| /JR/                | 5 9 4 8 6 4 8   |      | Kahn, et al    |       |              |                                       |
| /JR/                | 5 9 4 5 2 8 3   |      | Kwok, et al    |       |              |                                       |
| /JR/                | 5 9 4 5 5 2 6   |      | Lee, et al     |       |              |                                       |
| /JR/                | 5 1 1 8 8 0 1   |      | Lizardi, et al |       |              |                                       |
| /JR/                | 5 1 3 0 2 3 8   |      | Malek, et al   |       |              |                                       |
| /JR/                | 4 6 8 3 2 0 2   |      | Mullis, et al  |       |              |                                       |

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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| /JR/ | Moan, J., et al., "Porphyrin photosensitization and phototherapy," <u>Photochem. Photobio.</u> 43:681-690 (1986)  |
| /JR/ | Mujumdar, R.B., et al., "Cyanine dye labeling reagents containing isothiocyanate groups," <u>Cytometry</u> 10:11-19 (1989)  |
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| /JR/ | Nichols, et al., "A universal nucleoside for use at ambiguous sites in DNA primers," <u>Nature</u> 369:492-493 (1994)   |
| /JR/ | Okayama, H., et al., "High efficiency cloning of full length cDNA," <u>Mol. Cell. Biol.</u> 2:161 (1982)  |

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| /JR/                | 5 8 6 6 3 3 6   |      | Nazarenko, et al |       |              |                                       |
| /JR/                | 6 1 1 4 3 5 0   |      | Randall, et al   |       |              |                                       |
| /JR/                | 6 1 1 0 6 3 0   |      | Reddy, et al     |       |              |                                       |
| /JR/                | 6 0 0 1 5 7 3   |      | Roalent, C.      |       |              |                                       |
| /JR/                | 5 7 0 7 5 5 9   |      | Schaap, et al    |       |              |                                       |
| /JR/                | 6 3 2 3 3 3 7   |      | Singer, et al    |       |              |                                       |

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|   | Applicants: Ilan, et al          |                       |
|   | Filed: January 23, 2004          | Group: Not yet known  |

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